

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

NATIONAL INFUSION CENTER
ASSOCIATION *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

Case No. 1:23-cv-00707-DAE

**DEFENDANTS' NOTICE OF SUPPLEMENTAL
AUTHORITY IN SUPPORT OF MOTION TO DISMISS**

Defendants respectfully submit this Notice regarding a recent factual development that is relevant to the Article III standing arguments in Defendants' motion to dismiss, ECF No. 39.

In response to Plaintiffs' (belated) theory of standing relating to possible future financial harm in connection with the price of Stelara, Defendants explained that "according to public reporting (and statements by the manufacturers themselves), the launch of a biosimilar competitor to Stelara is expected no later than early 2025." Defs.' Mot. to Dismiss Reply at 8, ECF No. 49 (citation omitted). That possibility—unaccounted for in Plaintiffs' filings—was significant because, as Defendants have explained, "[i]f those predictions are realized, Stelara will be deselected, and negotiated prices will *never* take effect for the administration of Stelara under Part B. *See* 42 U.S.C. § 1320f-1(c)." *Id.*

Those predictions are now, in fact, beginning to be realized. Earlier this week, the Food and Drug Administration approved Wezlana, a biosimilar competitor to Stelara manufactured by Amgen, Inc.¹ *See* News Release: *FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases* (Oct. 31, 2023), <https://perma.cc/5X69-LR3A>. The approval of Wezlana underscores the degree to which

¹ Amgen, Inc. is no stranger to this litigation. *See* Decl. of Patrick Costello, ECF No. 35-6.

Plaintiffs' standing theory relies on "unsupported speculation about harms NICA's members might suffer 'no later than 2028,'" Defs.' Mot. to Dismiss Reply at 1 (quoting Pls.' Opp'n at 13, ECF No. 47), which cannot support Article III standing.

Date: November 2, 2023

Respectfully submitted,

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